

## **REMARKS**

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

### **Claim Amendments**

Claim 1 has been amended to recite that the base does not comprise agar. Support for this limitation is found on page 3, lines 14-16 of Applicants' original specification.

New claims 3-8 have been added to the application. Support for these claims is found on page 8, lines 8 to 16, and the examples of Applicants' original specification.

Accordingly, no new matter has been added to the application by these amendments.

### **Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

The rejection of claims 1 and 2 as being indefinite under 35 U.S.C. § 112, second paragraph is respectfully traversed. The Examiner states that Applicants' previous arguments concerning this rejection have been fully considered but are not found to be persuasive. The Examiner states that the examples set forth in Applicants' specification are actually different names of medicines usually used in Japan, and these medicines encompass many ingredients, not just one herbal extract. The Examiner states that unless Applicants are able to specifically indicate in the claim what is the herbal medicine, the claims are rendered indefinite.

Applicants again respectfully disagree with the Examiner's position. Initially, Applicants respectfully assert that it is improper for the Examiner to require Applicants to identify the herbal medicine. As clearly set forth in the specification, Applicants' invention is not limited by the particular Chinese herbal medicine chosen. As mentioned in the prior response, it appears that the Examiner's position regarding this issue relates more to the breadth of the claim than to the definiteness of the claim. MPEP 2173.04 clearly states that the breadth of a claim is not to be equated with indefiniteness.

Further, the terms "Chinese herbal medicine" and "Chinese medicine" are used in the specifications and claims of other U.S. patents, such as U.S. Patent Nos. 4,528,192,

7,273,628, and 7,255,885. Copies of these patents are enclosed herewith. Please see claim 1 of U.S. '192, claims 1-8 of U.S. '628, and claims 1-5 of U.S. '885. Therefore, it is evident that these terms do not render a claim indefinite.

For these reasons, Applicants respectfully assert that the rejection is untenable and should be withdrawn.

#### **Consideration After Final Rejection**

Although this amendment is presented after final rejection, the Examiner is respectfully requested to enter the amendments and consider the remarks, as they place the application in condition for allowance.

#### **Patentability Arguments**

The patentability of the present invention over the disclosure of the reference relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

#### **Rejection Under 35 U.S.C. § 103(a)**

The rejection of claims 1 and 2 under 35 U.S.C. § 103(a) as being unpatentable over Fukui et al. (U.S. 6,277,395) is respectfully traversed.

The Examiner takes the position that Fukui et al. teach a swallowing-assistive drink for medicines with adhesive paste of 0.02% carrageenan, 0.05% weight locust bean gum, 0.01% weight xanthan gum, that can be mixed with powders of Chinese medicines. The Examiner admits that the reference does not teach the amount of Chinese medicine, or adding the ingredients in the amounts claimed by Applicants. The Examiner takes the position that the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Thus, the Examiner states that absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicants' invention.

Applicants' invention relates to a Chinese herbal medicine composition in the form of jelly, which hardly causes syneresis, is superior in the preservative stability, is

broadly applicable to a Chinese herbal medicine and is orally taken without taking care of the bitter taste of the medicine. More specifically, Applicants' invention relates to a Chinese herbal medical composition in the form of jelly, comprising a Chinese herbal medicine in a base, wherein the Chinese herbal medicine is present in an amount less than 60 w/w% per total amount of the composition, and the base comprises a combination of carrageenan, carob bean gum and xanthan gum. Further, the composition comprises 0.01 to 10.0 w/w% carrageenan, 0.01 to 10.0 w/w% carob bean gum, and 0.01 to 10.0 w/w% xanthan gum, the base does not comprise a phosphate buffer, and the jelly does not comprise agar.

The invention of Fukui et al. relates to a swallowing-assistive drink for medicines containing carrageenan, locust bean gum, xanthan gum and so on, as an adhesive paste. The object of the invention of Fukui et al. is to prevent the bitter taste of the medicines and to allow for the medicines to be taken easily.

Column 4, lines 16 to 23 of Fukui et al. states:

Further, the swallowing-assistive drink obtained as mentioned above can be taken together with various medicines: after keeping medicines in a mouth, the swallowing-assistive drink maybe poured into the mouth instead of water and swallowed together with the medicines or after premixing of the medicines with the swallowing-assistive drink, the obtained mixture (liquid) may be poured into the mouth and swallowed.

Further, as indicated by the Examiner, Fukui et al. also mention, "Mixing powders of Chinese medicines with the present swallowing-assistive drinks prevented the bitter taste from spreading in the mouth and made it easy to take them." (See column 8, lines 24 to 27 of the reference.)

The swallowing-assistive drink of Fukui et al. has an enwrapping-function, and the viscosity of the swallowing-assistive drink decreases when heated up to the body temperature (37°C) to lose its enwrapping-function. (Please see column 7, lines 54 to 63 of the reference.)

As explained above, it is clear that the invention of Fukui et al. does not relate to a preparation (drink) containing medicines, especially Chinese herbal medicines, which can

be preserved for long term. Furthermore, it is evident that such a composition containing Chinese medicines is not taught or suggested by the cited reference.

The present inventor has carried out experiments, as shown in the enclosed Rule 1.132 Declaration, to confirm that contrary to Applicants' invention, the preparation containing a Chinese herbal medicine according to the invention of Fukui et al. is not suitable for long term preservation.

Specifically, Samples a, b and c were prepared by mixing different amounts of Kakkon-to (the most common Chinese herbal medicine) with the ingredients set forth in embodiment 1 of Fukui et al. The results, shown in Table 3 of the Declaration, demonstrate that the syneresis of Samples a, b and c is much greater than that of the preparation of the presently claimed invention (Sample A, which is a preparation of Applicants' example 2).

Applicants believe that one of the reasons for the difference in syneresis between Sample A and Samples a, b or c is due to the use of agar in the ingredients of Samples a, b or c. It is reported that the use of agar in a jelly preparation causes syneresis. (Please see page 3, lines 14-16 of Applicants' original specification.) Applicants note that claim 1 has been amended to exclude agar from the recited jelly.

Additionally, as shown in Tables 4 and 5 of the Declaration, with regard to strength of gel, the preparations (Samples a, b and c) of Fukui et al. are far inferior to the preparation of the present invention (Sample A.)

Thus, Applicants have confirmed that the preparation of Fukui et al., when it contains medicines, can not be used as a preparation with long term preservation. Further, Applicants have demonstrated unexpected results based upon the claimed formulation.

For these reasons, it is clear that Applicants' claims are patentable over the cited reference.

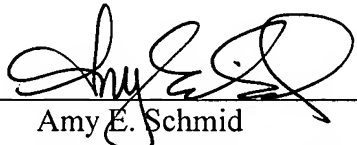
**Conclusion**

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

Tsunehiro FUKUCHI et al.

By:   
Amy E. Schmid  
Registration No. 55,965  
Attorney for Applicants

AES/nrj  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
December 28, 2007